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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,663

02/27/2004

Rainer Gruening

136-36

3625

23869 7590 04/01/2008
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EXAMINER

CHONG, YONG SOO

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/788,663	Applicant(s) GRUENING ET AL.	
	Examiner YONG S. CHONG	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-32 and 34-52 is/are pending in the application.
- 4a) Of the above claim(s) 37, 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-32, 34-36, 38, 41-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/10/2008 has been entered.

Claim(s) 1-23, 33 have been cancelled. Claim(s) 52 has been added. Claim(s) 24-32, 34-52 are pending. Claim(s) 37, 39-40 have been withdrawn. Claim(s) 24, 29-30 have been amended. Claim(s) 24-32, 34-36, 38, 41-52 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below as a result of the new claim amendments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-32, 34-36, 38, 41-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 11/416,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde is disclosed for the purpose of inhibiting the intrusion of micro-organisms into a body cavity in the preamble.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's request to file a terminal disclaimer once the instant application is allowed, is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 24-32, 34-36, 38, 41-50, 52 are rejected under 35 U.S.C. 103(a) as being obvious over Beckman et al. (US Patent Application 2002/0015697 A1).

The instant claims are directed to a method of inhibiting the intrusion of microorganisms into a body cavity of a mammal comprising applying into the body cavity a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde.

Beckman et al. teach methods, compositions, and kits for reducing a microbial population on a surface (abstract), such as the epidermal skin, mucosal surface, a wound, an abrasion, a burn, or a damaged region of tissue (section 0009). Other medical applications include the skin of a patient, teat of a dairy cow, oral cavity, vaginal cavity, and other living tissues of human beings (section 0078). The composition comprises transition metals prepared in water (section 0043), iodine, glutaraldehyde (section 0049), polyurethanes (section 0051), chitosan (section 0052), polyvinylpyrrolidone (section 0145), parabens (section 0149), water, alcohol, and dyes (section 0155). The antimicrobial compositions can be applied with a sponge, a mop, a cloth, or any other of a variety of techniques known to one of skill in the art of

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disinfection (section 0055). Furthermore, a range of concentrations of free iron can be employed in the methods for reducing a microbial population within an aqueous solution. For example, the free iron can be provided at a concentration as low as between about 0.1 μM to about 1 M free iron. Higher concentration of stress inducer may also be of particular use in some embodiments (sections 0071 and 0092).

Example 3 discloses the use of range of concentrations for a stress inducer (Figure 5). Another example discloses 100 mM iron citrate and between 0.01% to 15% chitosan. Optionally, the composition comprises between about 0.01% to 10%, preferably about 1% chitosan (section 0158).

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimal or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." *In re Peterson*, 315 F. 3d at 1330, 65 USPQ 2d at 1382; It has been held that it is within the skills in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 1980) MPEP 2114.04

It is obvious for one of ordinary skill in the art to use O-carboxymethyl chitosan and ethyl or isopropyl alcohol since the genus chitosan and alcohols were disclosed in

the prior art. Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

However, Beckman et al. fail to disclose a single example of a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde.

It would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to formulate a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde for the method of inhibiting the intrusion of microorganisms into a body cavity.

A person of ordinary skill in the art would have been motivated to formulate a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, and glutaraldehyde because of the reasonable expectancy of success in inhibiting the intrusion of microorganisms into a body cavity.

Claim(s) 51 is rejected under 35 U.S.C. 103(a) as being obvious over Beckman et al. (US Patent Application 2002/0015697 A1) as applied to claims 24-32, 34-36, 38, 41-50, 52 in view of Stoner (US Patent 4,925,033).

The instant claims are directed to a method of inhibiting the intrusion of microorganisms into a body cavity of a mammal comprising applying into the body

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cavity a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde.

Beckman et al. teach as disclosed above, however, do not teach spermicide in the composition.

Stoner teaches that a microbicidal cleanser composition to be used during sexual contact (abstract) so as to prevent the transmission of sexually transmitted diseases. This composition may also be in the form of contraceptives, such as coating fluids (foams, creams, jellies) to be used on the genitals. A well-known composition of the above type is nonoxynol-9, a spermicidal compound that also acts as an anti-microbial agent (col. 1, lines 19-58).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine the antimicrobial composition disclosed by Beckman et al. with the spermicidal composition disclosed by Stoner.

A person of ordinary skill in the art would have been motivated to combine the antimicrobial composition disclosed by Beckman et al. with the spermicidal composition disclosed by Stoner because: (1) both compositions are disclosed to possess antimicrobial properties; (2) both compositions are to be used on the genitals, such as the vaginal cavity; (3) Stoner discloses that antimicrobial compositions comprising spermicides are used to prevent sexually transmitted diseases; and (4) Stoner discloses nonoxynol-9, a well-known spermicidal compound that also acts as an anti-microbial agent. Therefore, the skilled artisan would have had a reasonable expectation of

success in preventing STDs by administering a composition comprising polyvinylpyrrolidone, parabens, O-carboxymethyl chitosan, polyurethane, spermicide, and glutaraldehyde.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... The idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Response to Arguments

Applicant argues that the "viscous gels" disclosed by Beckman are not equivalent structurally or rheologically to the "fully reversible" hydrogels of the present invention. The specific ratios of the constituent ingredients are critical, since a "fully reversible" hydrogel would not form without such ratios. Thus, Beckman teaches away from the hydrogels of the present invention.

This is found not persuasive because Beckman's compositions are taught to be generally in the form of gels (section 0058). It is noted that any gel has some sort of viscosity to it since gels inherently have a high resistance to flow. Furthermore, it is Examiner's position that the gels taught by Beckman are also "fully reversible" since every component of the present composition is disclosed by Beckman.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable

weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

The Gruening Declaration under 37 CFR 1.132 filed 2/12/2008 is insufficient to overcome the rejection of claims 24-32, 34-36, 38, 41-52 based upon Beckman et al. (US Patent Application 2002/0015697 A1) and Stoner (US Patent 4,925,033) as set forth in the last Office action because the Gruening Declaration does not provide any factual evidence for a showing of nonobviousness of the instant rejection.

The Gruening Declaration simply states that it is unexpected and surprising that the instant hydrogels exhibit certain sanitizing and disinfecting activity without the inclusion of antimicrobial/antibiotics. This is not commensurate with the scope of the claims because the instant claims do not preclude the use of any antimicrobial/antibiotics. Furthermore, the Gruening Declaration does not provide a side-by-side comparison with the closest prior art to show that the instant ranges are critical to the invention. Therefore, the Gruening Declaration is simply an opinion that states that the gels disclosed by Beckman are not "fully reversible," which is not convincing since all of the components of the instant composition are accounted for.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Finally, Applicant somehow argues nonobviousness since Beckman uses transition metals in the composition, while the instant hydrogel possesses sanitizing and disinfecting activity without the inclusion of antimicrobials/antibiotics.

This is not persuasive because the instant claims use the open transitional claim language of “comprising,” which does not preclude the inclusion of transition metals as taught by Beckman.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617